REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

1. STATUS OF CLAIMS AND FORMAL MATTERS

Please find attached hereto the priority documents, Japanese Patent Applications 2001-287698, filed September 20, 2001, and 2002-177666 filed June 18, 2002, attached hereto which have been fully translated into English.

The Abstract has been amended to provide a more clear and concise description of the disclosure. Particularly, use of the legal phrase "said" has been omitted. No new matter has been added.

Claims 25-30, and 32-40 are under consideration in this application. Claims 31 and 40 have been cancelled.

Claims 33 and 34 have been amended to recite to "female non-human animals" instead of "female non-animals. Claim 40 has been canceled pursuant to Examiner's double patenting concerns. All other previous claims were withdrawn without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Applicants reserve the right to pursue the subject matter of cancelled claims in continuing application.

No new matter has been added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§101, 102, 103 or 112. Rather, these additions are made simply to correct minor errors.

2. THE DOUBLE PATENTING REJECTION IS OVERCOME

Claim 40 was allegedly directed to an invention not patentably distinct from claims 1-18 of commonly assigned U.S. Patent No. 6,806,252 (the '252 patent). As mentioned above, claim 40 has been canceled thereby obviating the obviousness-type double patenting rejection.

3. THE REJECTIONS UNDER 35 U.S.C. § 101 ARE OVERCOME

Claims 25-30 were rejected as allegedly being directed to non-statutory subject matter. The claims have been amended to recite to a "transgenic" animal model having bone pathology. Claims 25-30, as amended, are directed to patentable subject matter. Therefore, because the amendments to claims 25-30 obviate the Section 101 rejection, reconsideration and withdrawal of the Section 101 rejection are respectfully requested.

4. THE REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, ARE OVERCOME

Claims 26-29, 31-34 and 36-38 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 26, 32, and 34 are drawn to an animal model "wherein the animal expresses one or more bone pathology of any vulnerability of bone tissue, change of bone morphology or delay in bone growth". The Office Action alleges that an animal cannot express bone pathology, but can only show pathological changes in bone morphology. Further, the Office Action alleges that the specification does not make clear what the differences are between "any vulnerability of bone tissue" and "changes in bone morphology". Finally, while the claims encompass any increase or decrease in "any vulnerability of bone tissue, change of bone morphology or delay in bone growth", it is allegedly unclear how a decrease in "any vulnerability of bone tissue" is pathological.

Claim 26 has been amended to recite to a transgenic non-human animal that overexpresses regucalcin wherein the animal expresses one or more changes in bone pathology comprising vulnerability of bone tissue, change of bone morphology or delay in bone growth. As claims 32 and 34 depend from claim 26, the amendments to the language of claim 26 thereby obviate these claim rejections.

The Office Action further alleges that the "metes and bounds" of claims 31 and 33 cannot be determined from the specification. It is allegedly unclear from the specification if these claims are intended to encompass a transgenic regucalcin animal or an animal transgenic for any other gene that is subsequently transfected with a regucalcin gene. The claims as amended now reflect "A transgenic animal model...", which encompasses the subject matter of claim 31, and claim 31 has been cancelled, thereby obviating the rejection in part. In addition, claim 33 now depends

from claim 25, which recites to a transgenic animal model having bone pathology wherein the animal model is a non-human animal that overexpresses regucalcin and shows bone pathology.

The Office Action contends that claims 27-29 and 36-38, drawn to a "measurement estimation", are unclear. It is allegedly uncertain from the specification if these claims are intended to indicate that measurements of bone morphology or biochemistry are to be taken, or if they are merely to be estimated. These claims have been amended to eliminate the term "estimation" thereby making it clear that the claims are intended to indicate that measurements of bone morphology or biochemistry are to be taken. These amendments thereby obviate the rejections to these claims.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, are respectfully requested.

5. THE REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH, ARE OVERCOME

Claims 25-40 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly lacks enablement. Claims 31 and 40 have been canceled thereby obviating the rejection in part. The Office Action contends that the specification does not reasonably provide enablement for any non-human animal that overexpresses regucalcin and shows bone pathology, a method of using said animal in a screening method for preventative and therapeutic agents, and a therapeutic or preventative agent. The presently claimed invention now recites to "A transgenic animal model..." This amendment is believed to overcome the enablement rejection under §112, first paragraph.

Further, according to the Office Action, the specification also allegedly fails to provide adequate guidance and evidence for the production of any transgenic animals overexpressing any regucalcin, which causes bone pathology other than the transgenic regucalcin rat with bone loss, in view of the contention that the art of transgenics at the time of filing was unpredictable.

For the reasons that follow, Applicants respectfully urge that the application, as filed, is adequately enabled. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

As the Office Action points out, the specification does provide adequate guidance and evidence for the production of the claimed transgenic rat model that overexpresses regucalcin

and shows bone pathology, a method of the transgenic rat model in a screening method for preventative and therapeutic agents, and a therapeutic or preventative agent.

The MPEP indicates in Section 2164.02 that "compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed." Furthermore, the MPEP states that "because only an enabling disclosure is required, applicant need not describe all actual embodiments." Applicants respectfully point out that working examples presented in the specification, along with the description, would allow one skilled in the art to practice the full scope of the claimed transgenic non-human animal model without undue experimentation.

The Examiner has reached the conclusion that undue experimentation would be required without providing analysis of the claims under the Wands factors. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. As stated in the MPEP, Section 2164.01(a), all of these factors must be weighed when arriving at a determination of whether necessary experimentation is undue. For example, such factors include the level of one of ordinary skill and the level of predictability in the art. Applicants submit that the techniques used to generate and use a transgenic non-human animal model are predictable and well-known to one of ordinary skill in this art and that one of ordinary skill in this art would be able to accomplish said preparation without undue experimentation.

The Examiner's attention is respectfully invited to some case law under the first paragraph of Section 112. First, it is a well known principle that claims must be read in light of the specification. See In re Marosi, 710 F2d 799, 218 USPQ 289 (Fed. Cir. 1983). Second, it has been determined that the claims need not be limited to preferred embodiments in the specification. It is improper, according to In re Goffe, 191 U.S.P.Q. 429, 431 (CCPA 1976), to limit the claims of an application to the specific examples in the specification under the guise of lack of enablement:

> To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials . . . would not serve the constitutional purpose of promoting, progress in the useful arts.

Third, it is urged that the subject matter in the claims is not broader than the enabling disclosure. Applicants respectfully submit that the claims are more than adequately supported by

the specification. There is no particular number of examples which makes specific claim language adequate or enabled. Indeed, enablement is not even related to the number of examples in the specification. In In re Borkowski, 164 USPQ 642, 646 (CCPA 1972), the court stated:

> There is no magical relation between the number of representative examples and breadth of the claims . . . the number and variety of examples are irrelevant if the disclosure is 'enabling' and sets forth the 'best mode contemplated'.

Moreover, "the law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 USC §112". Staehelin v. Secher, 24 USPQ2d 1513, 1516 (Bd.Pat.App.&Int. 1992) Indeed, a specification need not disclose–and best omits—that which is well known in the art. In re Buchner, 929 F2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991)

The Examiner is also respectfully reminded that it has been held that the specification must be accepted as enabling of the invention under 35 U.S.C. §112, unless doubt as to the truth/accuracy of the statements made with the specification is raised. In re Marzocchi, 169 U.S.P.Q. 367 (CCPA 1971):

> It is incumbent upon the Patent Office . . . to explain why it doubts the truth or accuracy of any statements in supporting disclosure and to backup assertions of its own with acceptable evidence or reasoning which is inconsistent with the contended statements.

Therefore, the specification has provided guidance and enabling disclosure to the claimed transgenic non-human animal model and thus, to the full scope of the claims.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, are respectfully requested.

6. THE REJECTIONS UNDER 35 U.S.C. § 102 ARE OVERCOME

Claims 25-35 are rejected under 35 U.S.C. § 102(a), as allegedly being anticipated by Yamaguchi *et al.* (J. Cell. Biochem. (2002) 86: 520-529). The Office Action contends that the Yamaguchi reference shares co-authorship with the inventor of the instant application. However, the Yamaguchi reference contains other entities, specifically Y. Morooka, H. Misawa, Y. Tsurusaki, and R. Nakajima, who are not listed as inventors of the instant invention. Therefore,

the Examiner considers the Yamaguchi reference to have been written by a different inventive entity than that of the instant invention.

It is submitted that Yamaguchi *et al.* is not a prior art document. Attached hereto is a Declaration under 35 C.F.R. §1.132 (hereinafter "Declaration"). The Declaration signed January 27, 2006 states that Yamaguchi *et al.* is not the work of others as defined by 35 U.S.C. §102(a). The Declaration is sufficient to overcome the grounds of rejection of claims 25-35 under 35 U.S.C. §102(a) because the Declaration clearly states that Y. Morooka, H. Misawa, Y. Tsurusaki, and R. Nakajima did not make an independent inventive contribution to the invention claimed in this application. Should the rejection be maintained, the Examiner is requested to indicate how the Declaration fails to successfully overcome the grounds of rejection.

Claim 40 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Downs, et al. (Calcif. Tissue Int. (1999) 64: 463-469). Claim 40 has bee canceled thereby obviating the rejection.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 102 are respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains an impediment to allowance, a further interview with the Examiner is respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks, amendments and Declaration, the application is believed to be in condition for allowance. Favorable reconsideration of the application, and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the under signed to advance prosecution.

Respectfully submitted,
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